

Hiner, Elizabeth E

From: phecht@bcbs-ga.com
Sent: Thursday, May 20, 1999 10:15 AM
To: BHINER@orahq.ora.fda.gov
Subject: Objection/M.O.U. Proposed by FDA

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May 20, 1999

Elizabeth Hinder, R.Ph.
Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Ms. Hiner:

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

I use natural progesterone which makes a tremendous difference in my (formerly) ongoing, monthly 4-day-long migraine headaches. Natural progesterone relieves the nausea and pain associated with these "hormonal" headaches (during menses). Natural progesterone has given me back 4 days of my life every month so that I can work at my regular job, raise my teenage son, be present for his sports events (I'm a single mother), and perform my usual community service activities—all without "calling in sick" or relying upon unnatural drugs (Imetrex) to stop a headache.

Every woman in the country, especially the large population of Baby Boomers who are now going through, OR those who will go through, menopause need NATURAL COMPOUNDED HUMAN HORMONES desperately. Human hormones alleviate not only migraines but sleeplessness, fatigue, forgetfulness, and most importantly the negative, unnatural side effects from "horse derived" hormones (Premarin, Premphase, Prempro, etc.).

Please consider my very serious objections to FDA intervention in this matter. It is already difficult enough to talk a medical doctor into trying something other than Premarin, Prempro or Premphase. In addition, with the majority of medical doctors being male, they have NO IDEA how seriously peri-, pre- or post-menopause can rob a woman of her normal quality of life.

Sincerely,

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